



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	Art Unit:
Bjorn NEXO)	
)	Examiner:
)	
Serial No.: 10/519,505)	Washington, D.C.
)	
Filed: June 27, 2003)	August 11, 2005
)	
For: DISEASE RISK ESTIMATING)	Docket No.: NEXO1
METHOD USING SEQUENCE...)	

#4

INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231

S i r :

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:

[] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application. See 37 CFR 1.97(b).

[X] B. before the mailing date of a first office action on the merits. See 37 CFR 1.97(b).

[] C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii"

below). See 37 CFR 1.97(c).

[] i. Counsel certifies that, upon information and belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

[] ii. A check for the fee set forth in 1.17(p), presently believed to be \$180, is enclosed (check no. _____).

[] D. after (A), (B) and (C) above, but before payment of the issue fee. Applicant petitions under 37 C.F.R. 1.97(d) for consideration of this IDS. A check for the fee set forth in 1.17(i)(1), presently believed to be \$130 is enclosed (check no. _____). Counsel certifies that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

[] E. As a submission in accordance with the transitional procedure for limited examination after final rejection pursuant to 37 CFR \$1.129(a). Pursuant to MPEP \$706.07(g), page 700-46, col. 2 (February 2000), this IDS is treated as if filed with a period set forth in 37 CFR \$1.97(b)

and considered without the petition and petition fee required by 1.97(d).

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO-1449) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document is attached, except as explained below.

[] While an IDS filed under \$1.97 must contain a "list of all patents, publications or other information submitted for consideration by the Office", see \$1.98(a) (1), the only requirement for the list is that it provide the information set forth in \$1.98(b). There is no requirement that a form PTO-1449 be used (MPEP \$609 merely says that use of this form is "encouraged"). Counsel has used a list provided to him by Applicants, and not transferred the information to a PTO-1449, to avoid the risk of any inadvertent error in transferring the information.

[] A. Documents _____ are deemed substantially cumulative to documents _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.

[] B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

[insert serial number/filing date]

Applicants identify these documents by attaching hereto copies of the form PTO-892s and PTO-1449s from the files of the prior applications or a fresh PTO-1449 listing these documents, and request that they be considered and made of record in accordance

with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application. If copies of any of these documents cannot be found in the files of the prior applications, the Examiner is requested to so notify counsel before taking action in this case, so replacement copies can be submitted. While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged") and no prohibition on submitting a copy of a form PTO-1449 or form PTO-892 from a prior case. Indeed, the re-use of such forms is desirable as it avoids error in transferring the information, and evidences that the reference was considered in a prior application. A previously accepted PTO-1449, or an examiner-prepared PTO-892, necessarily complies with §1.98(b).

[X] 3. Documents AM and AT are not in the English language. In accordance with 1.98(c), Applicants state:

[X] documents AM and AT already contain an English language abstract, summary or claim set.

[] a publicly available abstract is attached to each of documents _____, and the source of each abstract is indicated thereon.

[] documents _____ are patents or published patent applications for which counterpart English language patents or patent applications exist, and are enclosed, as follows:

<u>Foreign Lang. Doc.#</u>	<u>English Lang. Doc.#</u>
[insert]	[insert]

[] applicants have prepared an English translation of

at least the pertinent portions of documents _____, and copies are attached.

[] A concise explanation of the relevance of documents _____ is found in the attached search report from the _____ Patent Office (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).

[] A concise explanation of the relevance of documents _____ is set forth as follows:
[Insert concise explanation of relevance]

4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

5. Other information being provided for the examiner's consideration follows:

[insert other information]

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

7. The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant



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Substitute for form 1449A/B TO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Complete if Known

Application Number	10/519,505
Filing Date	June 27, 2003
First Named Inventor	Bjorn NEXO
Group Art Unit	
Examiner Name	
Attorney Docket Number	NEXO1

Sheet	1	of	2
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U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA	US- 5,580,729	12-03-1996	VOGELSTEIN	
	AB	US- 6,005,088	12-21-1999	FUJIWARA et al	
	AC	US- 6,084,088	07-04-2000	SHEPPARD et al	
	AD	US- 6,235,280	05-22-2001	CHATTERJEE et al	
	AE	US- 2002/0022591	02-21-2002	ALGATE et al	
	AF	US- 2002/0028460	03-07-2002	PINKEL et al	
	AG	US- 2002/0040127	04-04-2002	JIANG et al	
	AH	US- 6,406,891	06-18-2002	LEGERSKI	
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	AI	CA 2,116,633	08-29-1995	JOUTEL et al		
	AJ	CA 2,116,628	08-29-1995	JOUTEL et al		
	AK	WO 95/16791	06-22-1995	POIRIER, J		
	AL	WO 96/32956	10-24-1996	THE REGENTS OF THE UNIVERSITY OF CALIFORNIA		
	AM	WO 01/27265	04-19-2001	UNIVERSITAT BREMEN		
	AN	WO 01/47957	07-05-2001	ZYMOGENETICS, INC.		
	AO	WO 02/02627	01-10-2002	ZYMOGENETICS, INC.		
	AP	WO 02/29107	04-11-2002	BOARD OF REGENTS		
	AQ	WO 02/057489	07-25-2002	RESPONSE GENETICS, INC.		
	AR	WO 02/061128	08-08-2002	RESPONSE GENETICS, INC.		
	AS	WO 02/100246	12-19-2002	BOARD OF REGENTS		
	AT	WO 03/004640	01-16-2003	TAIHO PHARMACEUTICAL CO. LTD		
	AU	WO 03/008643	01-30-2003	CANCER RESEARCH TECHNOLOGY LIMITED		
	AV	EP 1 146 054	10-17-2001	ONO PHARMACEUTICAL CO. LTD.		

Examiner
SignatureDate
Considered

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A/P

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2

of 2

Complete if Known

Application Number	10/519,505
Filing Date	June 27, 2003
First Named Inventor	Bjorn NEXO
Group Art Unit	
Examiner Name	
Attorney Docket Number	NEXO1

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	AW	A.M. Brewster et al., "THE ASSOCIATION BETWEEN POLYMORPHISMS IN THE XERODERMA PIGMENTOSUM GROUP D GENE AND RISK OF BREAST CANCER" American Journal of Epidemiology, vol. 153, no. 11, (2001), p. S198 "Abstract"	
	AX	Bergamaschi et al., "IASPP oncoprotein is a key inhibitor of p53 conserved from worm to human" Nature Genetics, vol. 33, (2003), pp. 162-167	
	AY	Bjorn Nexø et al. "A specific haplotype of single nucleotide polymorphisms on chromosome 19q13.2-3 encompassing the gene RAI is indicative of post-menopausal breast cancer before age 55." Carcinogenesis, vol. 24, no. 5, (2003), pp. 899-904	
	AZ	Dorota Butkiewicz et al. "Genetic Polymorphisms in DNA repair genes and risk of lung cancer." Carcinogenesis, vol. 22, no. 4, (2001) pp:593-597	
	BA	Eszter Rockenbauer et al. Association of chromosome 19q13.2-3 haplotypes with basal cell carcinoma: tentative delineation of an involved region using data for single nucleotide polymorphisms in two cohorts. Carcinogenesis, vol. 23, no. 7, (2002), pp. 1149-1153	
	BB	Jing Jie Yu et al. "AN ERCC1 SPLICING VARIANT INVOLVING THE 5'-UTR OF THE MRNA MAY HAVE A TRANSCRIPTIONAL MODULATORY FUNCTION" ONCOGENE (2001) 20. pp: 7694-7698.	
	BC	Marianne Dybdahl et al. "POLYMORPHISMS IN THE DNA REPAIR GENE XPD: CORRELATIONS WITH RISK AND AGE AT ONSET OF BASAL CELL CARCINOMA". CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION VOL. 8, (JANUARY 1999) pp: 77-81,	
	BD	Pengchin Chen et al. "Association of an ERCC1 Polymorphism with Adult-Onset Glioma." Cancer Epidemiology Biomarkers and Prevention, vol. 9, no. 8, (2000), pp. 843-847	
	BE	Richard Shen et al. "Nonconservative Amino Acid Substitution Variants Exist at Polymorphic Frequency in DNA Repair Genes in Healthy Humans." Cancer Research, vol. 58, no. 4, (1998), pp. 604-608	
	BF	Ulla Vogel et al. "POLYMORPHISMS OF THE DNA REPAIR GENE XPD: CORRELATIONS WITH RISK OF BASAL CELL CARCINOMA REVISITED." CARCINOGENESIS VOL.22 NO. 6 (2001) pp. 899-904.	
	BG	Ulla Vogel et al. "DNA REPAIR CAPACITY: INCONSISTENCY BETWEEN EFFECT OF OVER-EXPRESSION OF FIVE NER GENES AND THE CORRELATION TO MRNA LEVELS IN PRIMARY LYMPHOCYTES." MUTATION RESEARCH 461 (2000) pp: 197-210.	
	BH	Yang Jian-Ping et al. "Identification of a Novel Inhibitor of Nuclear Factor-κB, Re1A-associated Inhibitor." J. Biol. Chem., vol. 274, no. 22, (1999), pp. 15662-15670	
	BI	Yin Jiaoyang et al.: "Multiple Single Nucleotide Polymorphisms of Human Chromosome 19q13.2-3 Associate with Risk of Basal Cell Carcinoma." Cancer Epidemiology Biomarkers and Prevention, vol. 11, no. 11, (2002), pp. 1449-1453	
	BJ	Yin Jiaoyang et al. "Twelve Single Nucleotide Polymorphisms on Chromosome 19q13.2-3-13.3: Linkage Disequilibria and Associations with Basal Cell Carcinoma in Danish Psoriatic Patients." Biochemical Genetics, vol. 41, no. 1-2, (2003), pp: 27-37	

Examiner
SignatureDate
Considered

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.